UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/909,796	07/23/2001	Catherine Taylor	10799/13	2704

23838 7590 07/16/2002

KENYON & KENYON
1500 K STREET, N.W., SUITE 700
WASHINGTON, DC 20005

EXAMINER	
SCHMIDT, MARY M	

ART UNIT	PAPER NUMBER
1635	7

DATE MAILED: 07/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/909,796	Applicant(s) TAYLOR ET AL.	
	Examiner Mary Schmidt	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-86* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-86* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6, 10-11, 19-23, 30-33, 37-38 and 46-50, drawn to methods of modulating apoptosis in a cell comprising the step of administering to said cell an agent that inhibits apoptosis-induced eIF-5A function in said cell wherein the agent is a chemical drug (non-nucleic acid), classifiable in class 435, subclasses 325, 366 and 375.

II. Claims 1-9, 12-36 and 39-86, drawn to methods of modulating apoptosis in a cell comprising the step of administering to said cell an agent that inhibits apoptosis-induced eIF-5A function in said cell wherein the agent is an antisense or oligonucleotide; and antisense compositions, classifiable in class 435, subclasses 6, 325, 366, 375; class 536, subclasses 23.1, 24.31, 24.33, 24.5; and class 514, subclass 44.

2. The inventions are distinct, each from the other because of the following reasons: Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation since the invention of Group I is drawn to methods

of inhibiting apoptosis-induced eIF-5A via a non-nucleic acid chemical or drug and the invention of Group II is drawn to methods of inhibiting apoptosis-induced eIF-5A via an oligonucleotide, such as an antisense molecule. These inventions are distinct because the chemical drugs and the antisense oligonucleotides have different chemical, physical, and functional structures and operate differently to inhibit eIF-5A. The chemical drugs such as spermidine, 1,3-Diaminopropane, putrescine, 1,7-Diaminoheptane or 1,8-Diaminooctane are not nucleic acid based and do not operate to inhibit the eiF-5A like an antisense nucleic acid does. Antisense oliogonucleotides are nucleic acid molecules which operate via Watson-Crick base pair binding to the complementary nucleic acid in the target gene sequence. They are designed specifically based on a known target nucleic acid sequence and have variable lengths and modified compositions for increased utility. The small molecule drugs listed above do not have the flexibility of design like an antisense molecule to bind different regions of the target gene, and do not operate to down-regulate the gene expression based on an RNAseH cleavage mechanism like the antisense. These agents, the small molecule drugs and the antisense oligonucleotides, are capable of separate manufacture, use or sale as claimed, and are patentable (novel and unobvious) over each other (though they may each be unpatentable because of the prior art).

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their divergent classification and recognized divergent subject matter, and the search required for each of Group I or II is not required for the other Groups, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

4. **Should Applicant elect Group I, the following election of species is required:**

5. This application contains claims directed to the following patentably distinct species of the claimed invention: spermidine, 1,3-Diaminopropane, 1,4-Diaminobutane (putrescine), 1,7-Diaminoheptane, or 1,8-Diaminooctane.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-6, 10, 19-23, 30-33, 37 and 46-50 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. **Should Applicant elect Group II, the following further restriction is required:**

IIA. Claims 1-8, 12-13, 15-16, 30-35, 39-40, 42-43, 46-47 and 57-72, drawn to methods of modulating apoptosis in a cell comprising the step of administering to said cell an agent that inhibits apoptosis-induced eIF-5A function in said cell wherein the agent is an antisense or oligonucleotide targeted to eIF-5A; and antisense compositions to eIF-5A, classifiable in class 435, subclasses 6, 325, 366, 375; class 536, subclasses 23.1, 24.31, 24.33, 24.5; and class 514, subclass 44.

IIB. Claims 1-6, 9, 14, 17, 19-30, 33, 36, 41, 44-56 and 73-75, drawn to methods of modulating apoptosis in a cell comprising the step of administering to said cell an agent that inhibits apoptosis-induced eIF-5A function in said cell wherein the agent is an antisense or oligonucleotide targeted to DHS; and antisense compositions to DHS, classifiable in class 435, subclasses 6, 325, 366, 375; class 536, subclasses 23.1, 24.31, 24.33, 24.5; and class 514, subclass 44.

7. Inventions IIA and IIB are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different

functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. Both inventions are drawn to methods of modulating apoptosis via administration of an antisense or oligonucleotide. The claims of Group IIA are drawn to antisense oligonucleotides which target the eIF-5A gene directly. The claims of GroupIIB are drawn to antisense oligonucleotides which target the DHS gene directly, and which indirectly also effect eIF-5A function. Since the antisense of GroupIIA and GroupIIB target different genes, they are different in their nucleic acid sequence structure and thus operate differently. The oligonucleotides of Groups IIA and IIB are capable of separate manufacture, use or sale as claimed, and are patentable (novel and unobvious) over each other (though they may each be unpatentable because of the prior art).

8. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their recognized divergent subject matter, and the search required for each of Group IIA or IIB is not required for the other Groups, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). Although claims 1-6, 30, 33 and 46-47 are generic to both Groups IIA and IIB, examination on the merits of these claims will be limited to the elected invention, either methods and compositions comprising eIF-5A antisense oligonucleotides (Group IIA) or methods and compositions comprising DHS antisense oligonucleotides (Group IIB).

9. **Sequence election requirement upon election of either Group IIA or Group IIB for examination on the merits:**

In addition, Groups IIA and IIB detailed above read on patentably distinct sequences. Specifically, claim 61 in Group IIA and claim 75 in Group IIB are drawn to patentably distinct SEQ ID NOS.: Claim 61 having target eIF-5A SEQ ID NOS: 1, 3, 4 or 5; and Claim 75 having target DHS SEQ ID NOS: 6 or 8. Each sequence is patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For an elected Group drawn to nucleic acid sequences, the Applicant(s) must elect a single nucleic acid sequence (See MPEP 803.04).

MPEP 803.04 states:

"Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions with the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq."

It has been determined that 1(ONE) sequence constitutes a reasonable number for examination purposes under the present conditions. At present the huge number of submissions of claims directed to various sequences, such as nucleic acids or polypeptides, is so large that the

election of 1(one) sequence of this type is now deemed to be practically appropriate so as to not overwhelm the examination and search processes for such claims.

Examination will be restricted to only the elected sequence. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Mary M. Schmidt*, whose telephone number is (703) 308-4471.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *John LeGuyader*, may be reached at (703) 308-0447.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group Analyst, *Kay Pinkney*, whose telephone number is (703) 305-3553.

M. M. Schmidt
July 8, 2002

MM Schmidt